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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/560,075   | 12/09/2005  | Gang Zheng           | 1694.0580004/JMC/CMB | 9659             |
| 26111 7590 10/08/2008<br>STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.<br>1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |             |                      |                      |                  |
| EXAMINER   |             |                      |                      |                  |
| BLAND, LAYLA D   |             |                      |                      |                  |
| ART UNIT   |             | PAPER NUMBER         |                      |                  |
| 1623   |             |                      |                      |                  |
| MAIL DATE  |             | DELIVERY MODE        |                      |                  |
| 10/08/2008   |             | PAPER                |                      |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,075

**Applicant(s)**

ZHENG ET AL.

**Examiner**

LAYLA BLAND

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CIS)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December May 22, 2008 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed July 18, 2008, and amendment and response to the Final Office Action (mailed February 22, 2008), filed May 22, 2008 wherein claim 1 is amended and claims 3-24 and 26-36 are cancelled.

Claims 1, 2, and 25 are pending and are examined on the merits herein.

In view of Applicant's amendment submitted May 22, 2008, which incorporated specific structural definitions of BChIPP, BChIE6, and NIR664, the prior art rejection of the previous office action is withdrawn in favor of the new rejection presented below.

The provisional applications 60/476,648, 60/537,282, 60/540,700, and 60/548,240, upon which priority is claimed, fail to provide adequate support under 35 U.S.C. 112 for claims 1, 2, and 25 because of this application because none of the priority applications provides support for each of the structures presented in amended claim 1.

Thus, the filing date of claims 1, 2, and 25 is deemed to be the instant filing date, June 9, 2004. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

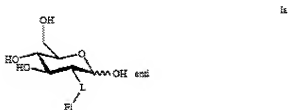
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tidmarsh et al. (US 6,989,140 B2, January 24, 2006, of record) in view of Fukuzumi et al. (J. Phys. Chem. A 2002, 106, 5105-5113).

Tidmarsh et al. teach methods for cancer and pre-cancer detection by increased uptake of deoxyglucose conjugates in cancerous and pre-cancerous cells [see abstract]. Cancerous and pre-cancerous cells exhibit an enhanced rate of uptake of glucose fluorophore conjugates [column 4, lines 38-41]. The conjugates can be derived by chemically modifying 2-deoxyglucose, which is taken into and accumulated in cancerous cells and pre-cancerous cells compared to normal cells [column 4, lines 42-49]. After allowing the fluorophore glucose conjugate to accumulate in the cancerous

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cells, an examination can be made with a camera or other device to view or capture the fluorescence [column 4, lines 49-54]. Preferably, the fluorophore fluoresces upon excitation of light in the range of about 500 nm to 900 nm [column 6, lines 24-31]. Preferred fluorophores include macrocyclic fluorescent dye compounds [column 8, lines 1-5]. The fluorophores can be attached to the deoxyglucose using, for example, a fluorophore isothiocyanate [column 9, lines 64-67] or a bifunctional linker group derived from  $\text{-NH}_2$ ,  $\text{NHNH}_2$ ,  $\text{-ONH}_2$ ,  $\text{-NHC(=O)NHNH}_2$ ,  $\text{-OH}$ ,  $\text{-CO}_2\text{H}$ , or  $\text{-SH}$  [column 10, lines 26-45]. The fluorophore deoxyglucose conjugate can have the formula shown below, where L is a linker group and FI is a fluorophore [column 15, 1a]:



The conjugates can be administered in forms suitable for oral administration or parenteral administration and can include pharmaceutical carriers [column 17, lines 13-49].

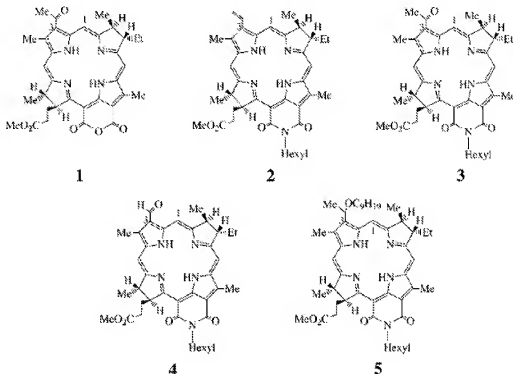
Tidmarsh et al. do not exemplify a glucose conjugate with the elected species BChlPP as recited in claim 1.

Fukuzumi et al. teach that the following stable bacteriochlorin compounds [page 5108, Chart 1] are highly promising for potential use in photodynamic therapy due to long-wavelength absorption [see abstract]. Conversion of the five-membered isocyclic ring present in chlorophyll *a* can be converted into a fused six-member isoimide or imide

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ring, extending the long-wavelength absorptions [page 5105, last paragraph].

Compounds containing the six-member imide ring were more stable in vivo than those bearing a fused anhydride or isoimide ring system [page 5106, first paragraph].



It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare glucose conjugates with bacteriochlorins such as compound 3 taught by Fukuzumi et al. Tidmarsh et al. teach that glucose conjugates with fluorophores, including conjugates linked by isothiocyanate as shown in instant claim 1, are useful for cancer detection and Fukuzumi et al. teach that compound 3 has ideal properties for photodynamic therapy, including fluorescence within the desired wavelength range taught by Tidmarsh et al. Compound 3 is very similar to BChlPP shown in claim 1, except for the group attached to the imide. Tidmarsh et al. teach the

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use of an isothiocyanate linker, such as the one shown in claim 1, for attachment to a 2-deoxyglucose molecule. Thus the skilled artisan could easily conceive of preparing a glucose conjugate of compounds taught by Fukuzumi et al. and could predict that the resulting conjugate would be effective for cancer detection and photodynamic therapy.

### ***Response to Arguments***

Applicant's arguments with respect to the rejection over Tidmarsh in view of Kozyrev have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Tuesday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/  
Examiner, Art Unit 1623